From the
INTERNATIONAL SEARCHING AUTHORITY



# PCT

To:

see form PCT/ISA/220

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

| | |
|---|---|
| | Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet) |
| Applicant's or agent's file reference<br>see form PCT/ISA/220 | **FOR FURTHER ACTION**<br>See paragraph 2 below |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/EP2004/052634 | 22.10.2004 | 22.10.2003 |

International Patent Classification (IPC) or both national classification and IPC
B65D75/34, B65D75/38, A61J1/03, B65D77/04, B65D5/50

Applicant
ALTANA PHARMA AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| Name and mailing address of the ISA: | Authorized Officer |
|---|---|
| European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465 | Appelt, L<br>Telephone No. +49 89 2399-2570 |

PCT/ISA/237

**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 12

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 12

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

| | | |
|---|---|---|
| the written form | ☐ | has not been furnished |
| | ☐ | does not comply with the standard |
| the computer readable form | ☐ | has not been furnished |
| | ☐ | does not comply with the standard |

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

## Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:

   ☒ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   **see separate sheet**

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-11,13-19

## Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 3,4,8-11,13-19 |
| | No: | Claims | 1,2,5-7 |
| Inventive step (IS) | Yes: | Claims | |
| | No: | Claims | 1-11,13-19 |
| Industrial applicability (IA) | Yes: | Claims | 1-11,13-19 |
| | No: | Claims | |

2. Citations and explanations

**see separate sheet**

**Re Item IV**

**Lack of unity of invention**

The present application relates to several groups of inventions which are not so linked as to form a single general inventive concept, contrary to Rule 13.1 PCT.

Claims 1 to 7, 14, 15 and 19 relate to the general construction of the outer package of a medicine pack having a plurality of blister units in the outer package each blister unit having a protective case

Claims 1, 2, 8 to 11, 13, 16, 17, 18 relate to the construction of the inner retaining means in the outer package of a medicine pack having a plurality of blister units in the outer package each blister unit having a protective case

Claims 1, 2 and 12 relate to the foldable and detachable construction of a series of blister units each having a protective case, the blister units forming part of a medicine pack and being contained in an outer package.

The common features of these three groups inventions are basically those of claim 1. Such a medicine pack is, however, commonly known (see in particular GB-A-2250978).

Since the problems to be solved by the three inventions and the features solving these problems are different, the different technical features cannot be considered to be corresponding special technical features as required by PCT Rule 13.2.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents :

D1: GB-A-2 250 978 (ANDREW ERNEST PARKER) 24 June 1992 (1992-06-24)
D2: US-A-5 242 055 (PORA ET AL) 7 September 1993 (1993-09-07)
D3: US-A-2 801 002 (VOLCKENING LLOYD IRWIN ET AL) 30 July 1957 (1957-07-30)
D4: US-A-5 219 116 (HEARNE ET AL) 15 June 1993 (1993-06-15)

D5: US-A-2 784 901 (WILCOX ISAAC L) 12 March 1957 (1957-03-12)
D6: US-A-3 910 487 (JAESCHKE ET AL) 7 October 1975 (1975-10-07)
D7: US-A-3 438 563 (PETER C. COLLURA ET AL) 15 April 1969 (1969-04-15)
D8: US-A-5 913 426 (LOTZ RENFRO ET AL) 22 June 1999 (1999-06-22)
D9: US-A-3 756 385 (STEINBOCK F,US) 4 September 1973 (1973-09-04)
D10: US 2002/175106 A1 (NEMOTO EIKO) 28 November 2002 (2002-11-28)
D11: EP-A-0 940 345 (DAVID S. SMITH PACKAGING LIMITED) 8 September 1999 (1999-09-08)

**Claims 1 and 2**

It is evident from Fig. 6 and Fig. 1 of the document D1 that the walls (13 and 15) of the blister unit, in use, serve as a protective case for the blister strips.

This blister unit can be unfolded in order to gain access to the products contained in the blisters and the units are undoubtedly contained in an outer package.

Accordingly, the present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

The package according to D1 is also constructed in such a manner that the units can be fixed inside the package.

Thus, the present claim 2 does also not meet the requirements of Article 33 (2) PCT, because its subject-matter is not novel.

It is submitted that the documents D2 and D3 also show medicine packs comprising all features of the present claims 1 and 2.

**Claims 3 to 7, 14, 15, 19**

It would appear that the features of the dependent claims and of claim 15 are so commonly known in the art of packaging that no inventive skill is necessary to apply them to an outer package of a medicine pack.

Nevertheless, it is pointed out that D1 also discloses the features of claims 5, 6, and 7 explicitly.

Only by way of example, reference is made to the documents D4, D5, D6 and D7 which show clamping strips (D4), removable covers (D5), hinged lids (D6) and complete packages wrapped in a film (D7).

It is also submitted that it is commonly known to incorporate an information leaflet in a medicine pack.

Accordingly, it appears that the combination of one or more of the dependent claims with claim 1 and/or claim 2 would, at least because of lack of an inventive step, not result in an independent claim meeting the requirements of Article 33 (3) PCT.

In consequence, this observation is valid in a correspondent manner to the independent claim 15 (which basically results from the combination of claims 1, 5 and 14).

**Claims 8-11, 13, 16-18**

Reference is first made to the document D8 which discloses retention means inside a carton for holding elongate rectangular objects. Such objects could undoubtedly also be blister units having a protective case. Accordingly, the skilled man would without any hesitation use such retention means in a package as it is known from, e.g., the document D2 in order to provide an outer package holding its contents even if the outer package is tilted to the side or even turned by 180°. In a corresponding manner, he could also choose to use the retention means as disclosed in D9, D10 or D11.

D8 explicitly discloses the features of the present claims 8 to 11 and 13.

Furthermore, it is submitted that the independent claims 16 to 18 differ from claim 15 in that the device for reclosing is replaced by the resilient tabs (claim 16), has the resilient tabs in addition to a closure (claim 17) or in addition to a detachable closure (claim 18).

As already indicated above, all these features (i.e. a closure device, resilient tabs, and/or a wrapper) will be applied in an outer package for receiving a plurality of blister packs by the skilled man in an obvious manner.

Accordingly, the claims 8 to 11, 13 and 16 to 18 do also not meet the criteria of Article 33 (1) PCT, because their subject-matter does not involve an inventive step in the sense of Article 33 (3) PCT.